

### **Remarks**

Applicant has carefully considered this Application in connection with the Examiner's Action, and respectfully requests reconsideration of this Application in view of the foregoing amendment, and the following remarks.

Claim 1 has been amended to more clearly define the oral suspension claimed by Applicant. Support for the amendment to Claim 1 can be found – at least – at page 2 and in Examples 3 & 4 of Applicant's disclosure. No new matter has been added.

Accordingly, Claims 1, 5, 7, 8, 9, 13, and 15 are presently pending in the Application, with Claims 1, and 15 being the independent claims.

#### ***I. Rejection under 35 U.S.C. § 112, First Paragraph***

Claims 1, 5, 7-9, 13 and 15 stand rejected under 35 U.S.C. § 112, First Paragraph as failing to comply with the written description requirement for use of the transitional phrase "consisting essentially of". (Office Action page 2).

In light of the amendments to Applicant's claims, the rejection is moot. As such, Applicant respectfully requests that the rejection of Claims 1, 5, 7-9, 13 and 15 under 35 U.S.C. § 112 be reconsidered and withdrawn.

#### ***II. Rejection of Claims under 35 U.S.C. § 103(a)***

The Examiner has rejected Claims 1, 5, 7 – 9, 13 and 15 under 35 U.S.C. § 103(a) as being unpatentable over De Bruijn (WO0010526) in view of Patel (US 20030180352) and in further view of Achong (US 20040162273). Applicant respectfully traverses the rejection.

In making the Section 103 (a) rejection, the Examiner cites DeBruijn as teaching a composition for administering an acid-sensitive active ingredient that is poorly soluble. The Examiner also cites Patel as teaching solid carriers to improve the delivery of active ingredients in pharmaceutical ingredients by masking the taste. The Examiner states that one skilled in the art would be motivated to combine DeBruijn and Patel to mask the unpleasant taste for the drugs disclosed.

The Examiner also turns to Achong for teaching a powder pharmaceutical composition that can be formulated to contain aesthetically pleasing flavor and sweetener ingredients when dissolved in beverages, such as cold water and apple juice. The

Examiner states that one skilled in the art would be motivated to combine Achong with DeBruijn and Patel to use apple juice to mask the unpleasant taste for the drugs disclosed.

Applicant respectfully submits that neither DeBruijn nor Patel teach, suggest, or provide motivation to use a crushed tablet of tegaserod, or apple juice as a beverage –as recited in Applicant's claims – to form a homogenous oral suspension capable of providing partitioned dosage of tegaserod. Neither DeBruijn nor Patel teach the use of crushed tablets of tegaserod containing a known and fixed amount of active ingredient as a component of a homogenous suspension, wherein the dosage of the active ingredient is capable of being partitioned, as expressly recited by Applicant's claims. Applicant's homogenous oral suspension is an alternative method of tegaserod administration which is especially suitable for partitioning a dosage of tegaserod and for a patient's use at home.

Applicant respectfully asserts that Achong fails to cure the defects of the DeBruijn and Patel combination. There is no teaching, suggestion, or motivation provided by Achong to use the superior dissolution properties of crushed tablets of tegaserod in apple juice, as recited by Applicant's claims. Most significantly, Achong fails to recognize that apple juice is preferable to a host of other aesthetically pleasing flavors and sweetener ingredients for specific and non-obvious reasons.

Applicant has discovered that apple juice has an unexpected advantage and superior results, specifically a superior dissolution profile, when compared to other masking agents discussed in the prior art, such as orange juice and apple sauce. See Example 3 of Applicant's specification where Applicant found that dissolution profile of the tegaserod with orange juice is less favorable, i.e. around 58% dissolution after 60 minutes. (See also Carrier et al. "*Stability and Compatibility of Tegaserod from Crushed Tablets Mixed in Beverages and Food*" American Society of Health-System Pharmacists, Inc. (2004), Pages 1138 (3d column), 1140 (3d column), and 1141 (middle column), attached hereto as Exhibit A).

Applicant has discovered that the dissolution of crushed tablets of tegaserod in apple juice was complete in five minutes and that the tegaserod was stable in apple juice for up to one hour at room temperature and up to three days when stored properly,

providing a superior dissolution profile when compared to orange juice. (See Example 3 of Applicant's specification; See Carrier, Page 1140)

Applicant's homogenous oral suspension – as expressly claimed – also overcomes the problem of administering tegaserod in a liquid formulation, complete with acceptable criteria for dosage, dissolution, stability and homogeneity. Current dosage formulations for tegaserod are available as 6 mg or 2 mg, but do not have a partition line. Thus, there is no possibility for a doctor to administer tegaserod in a particular dosage other than 6 mg or 2 mg. Particularly because Applicant's oral suspension of tegaserod is homogenous, the oral suspension of Applicant's claims is capable of providing a partitioned dosage of tegaserod.


Thus, in view of the foregoing remarks, the cited references of DeBuijn, Patel and Achong do not, singularly or in combination, teach, or suggest each and every claim limitation of Applicant's claims to support the Examiner's rejection under 35 U.S.C. § 103(a).

In view of the above, Applicant respectfully requests the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. §103.

### **III. Conclusion**

In view of the foregoing, Claims 1, 5, 7, 8, 9, 13, and 15 are in condition for allowance, and Applicant earnestly solicits a Notice of Allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration to this Amendment and Reply is respectfully requested.

Respectfully submitted,  
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Date: November 17, 2008

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